REMARKS

All of the previous claims have been cancelled and new Claims 75-95 have been added. Claims 75-84 are drawn to a method for reducing low density lipoprotein ("LDL") while not significantly reducing high density lipoprotein ("HDL"). Claims 85-95 are drawn to a dosage form for oral administration. The claims, as revised, recite a particularly preferred aspect of the invention. The method of Claim 75, requires administering over time a composition comprising theaflavin, theaflavin-3-gallate, theaflavin-3'-gallate, and theaflavin 3,3'-digallate. The mixture is administered in a quantity sufficient to reduce the LDL and not reduce the HDL over the time of its administration, where the administration is preferably at least 4 weeks (Claim 76) or 12 weeks (Claim 77). Claim 84 is a dosage form suitable for oral administration to a human subject that comprises the four compounds in an amount sufficient that, when administered over time, the LDL is reduced but the HDL is not significantly reduced. Support is found in Example 5 at pages 22-25 of Applicants' specification immediately preceding Table 3., which describes the double blind, randomized, pacebo-controlled, parallel-group trial. Specfic support is found at the paragraph on page 24 immediately preceding Table 3.

The claims reflect that part of the Applicants' invention is the discovery that the described mixture reduces the LDL over time while the HDL is not significantly reduced at the same time.

It is respectfully submitted that the subject matter as described in the new claims is patentably distinct from any of the references cited by the Examiner.

The Examiner had rejected the old claims under 35 U.S.C. 102(b) as being anticipated by the Vitasyn reference. The Vitasyn reference is a rambling, prophetic description of the benefits of drinking large quantities of green tea. However, there is nothing in the Vitasyn reference that suggests either the method of Claims 75-83 or the composition which provides the benefits as set forth in Claims 84-93. While the Vitasyn patent at page 3 (of the translation) indicates that "so-called phytochemicals (e.g. polyphenols) achieved particular importance recently as antioxidants," the authors go on to indicate that these phytochemicals also occur in certain types

of berries, garlic, citrus fruit, soy beans, and green tea. In Example 1, the authors refer to a Japanese cross-section study of 1,371 males. Supposedly, in that study, serum cholesterol and triglycerides were lowered from the "regular enjoyment of green tea." The best values were observed with a daily consumption of at least ten cups of green tea. No data is presented. The authors go on to say, at page 5, that green tea extracts "reduce triglycerides in rats." However, they don't indicate what those extracts might be, nor what the pattern of reduction of the triglycerides might be.. The authors do go on to say for epicatechin gallate and epigalacatechin gallate, a cholesterol-reducing effect and inhibition of the LDL oxidation were observed in animal tests. The authors further admit, at page 8, that the concentration of relative active ingredients (polyphenols) are subject to wide variations caused by the individual style of tea preparation. The compounds of epicatechin et al. are shown in their chemical structure at page 4 of the original German language patent application. Nothing is mentioned in the specification of the particular compounds that are the subject of Claims 75-95 in Applicants' invention. While the recommended uses, shown at page 11 of the translation, include prophylaxis in treatment of high cholesterol in elevated serum triglycerides, nothing is said as to the specifics of the compounds that are administered nor as to the results which might be seen. No data given as to the effect on HDL, i.e., the "good" lipoprotein. Claim 1 of the Vitasyn reference is rather unusual in that, after only talking about broadly polyphenols from tea, tea extracts and the catechins, suddenly the theaflavins are included in the list at Claim 1 without providing any support in the description.

Thus, as mentioned before, part of the claimed invention in the instant application is the discovery that by administering the mixture of theaflavins, as defined, over time and at levels taught in the specification, one sees a reduction in low density lipoprotein while not significantly reducing the high density lipoprotein. Nothing in the Vitazyn reference suggests a composition or method of administration, the would provide such a result administering the theaflavin mixture as defined over time, preferably 4 weeks and more preferably 12 weeks.

It is respectfully submitted that the Vitasyn reference clearly does not anticipate the method or composition claims of the instant invention.

Neither does the Vitasyn reference render the immediate claims obvious. Nothing in the Vitasyn reference suggests that the long-term administration, particularly four weeks or more, of the defines composition would result in the reduction of LDL but no significant reduction in HDL. Nothing in the Vitasyn reference would suggest such a result nor would it suggest such a method. It is therefore submitted that the Vitasyn reference does not make the claimed invention obvious.

The Examiner is also rejecting the claims under 35 U.S.C. 102(b) as being anticipated by the Abe et al. reference from the Japanese Journal of Food Chemistry. While, indeed, the disclosure of Abe suggests that the theaflavins shown as compounds 3-6 are excellent inhibitors of squalene epoxidase, the rate limiting enzyme of the cholesterol biosynthesis. There is nothing in the reference that would suggest the administration of a sufficient amount over time that would reduce the low density lipoprotein but not significantly reduce the high density lipoprotein. Nor would it suggest a composition that would achieve those results.

Thus, it is respectfully submitted that the subject matter claimed in new Claims 75-95 is patentably distinct from the Abe et al. reference as well as the Vitasyn reference and that the claims as rewritten should be allowed to issue.

IN presenting the new claims 75-95, it should be understood that Applicant reserves the right to pursue subject matter of the invention not encompassed by the pending claims in filing a continuing application during the pendency of the instant application. Applicant does not relinquish the right to pursue cancelled claimed subject matter or other subject matter that may be patentable and supported in the specification.

If the Examiner believes that a telephonic interview would be of use in dealing with the issues, he is invited to call the undersigned attorney at (650) 251-1142. The Examiner's attention is directed to the IDS filed 15 February 2005.

Respectfully submitted,

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